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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,137	05/22/2001	James W. Gautsch	BIO0038P	1270

7590 09/10/2002

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/10/2002 

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/863,137	GAUTSCH ET AL.
	Examiner	Art Unit
	Francisco C Prats	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 29 May 2001.

2a) This action is FINAL.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-20 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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#### DETAILED ACTION

The preliminary amendment filed May 22, 2001, has been received and entered.

Claims 21-29 have been cancelled.

Claims 1-20 are pending and are examined on the merits.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melendez et al (U.S. Pat. 5,464,773).

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Melendez discloses the preparation of nucleic acid from cells using the claimed oscillation frequencies and treatment durations. Melendez differs from the claims in not exemplifying a single specific embodiment wherein DNA is prepared from cellular material. Also, Melendez does not disclose the use of the specifically claimed biological samples in combination with a buffer containing detergent in the claim designated amounts. However, Melendez discloses that "[v]irtually any type of biological sample may be disrupted using the apparatus of this invention", including bacteria, fungi, plant cells and tissues, animal cells and tissues, protoplasts, spheroplasts and spores, and viruses and the like. See col. 2, lines 26-45. Moreover, Melendez discloses that a "further aspect of this invention involves the step of adding various surfactants and/or detergents to the liquid cell sample in order to enhance lysis", including at least one detergent recited in claim 40. See col. 5, lines 30-36. Thus, the artisan of ordinary skill clearly would have been motivated by Melendez to have obtained nucleic acid, including DNA, from the claim-designated biological sources using the claim-designated surfactants in the claim-designated amounts, the amount of detergent clearly being a

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result effective parameter routinely optimized by the artisan of ordinary skill.

Further still, applicant's selection of specific materials for the claimed beads or particles would have been considered obvious by the artisan of ordinary skill, the selection of a particular material being a matter of judicious choice on the part of the artisan of ordinary skill selecting from among a group of disclosed equivalents. Similarly, the selection of specific bead volumes, specific detergent amounts, etc., would have been considered by artisan of ordinary skill to have been matter of routine optimization, these parameters being routinely optimized in the art to effect a desired result.

Lastly, it is noted that none of the references disclose the specific clearance between the side of the container and the spherical beads contained within. However, as the claims currently read the particles "comprise" one bead. This open language encompasses a process using many particles. Given the fact that the artisan of ordinary skill the time of applicant's invention would expect at least some of the particles to be, at some time, within the claimed distance of the interior wall of the container, this limitation is properly deemed to be met by any of the references.

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The cited claims are therefore properly considered obvious.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zlobinsky et al (U.S. Pat. 5,567,050), the 1995-1996 Cole-Parmer Catalogue (pages 539 and 548, published 1994), and the 1988 Fisher Catalogue ("Cell Homogenizer MSK", page 609), in view of Moore et al (U.S. Pat. 4,295,613) and Murphy et al (EPO 0 288 618).

The Zlobinsky, Cole-Parmer, Fisher and Moore references all disclose apparatuses for the disruption of cells using oscillating energy. All of these references disclose that the oscillating energy is applied within the claimed frequencies. None of these references specifically discloses the recovery of DNA from the disrupted cells. However, the artisan of ordinary skill at the time of applicant's invention, viewing Murphy's disclosure of the recovery of DNA from cells disrupted by oscillating energy (see, e.g. abstract), would clearly have reasonably expected from that one could recover DNA from cells disrupted by the apparatuses disclosed in the Zlobinsky, Cole-Parmer, Fisher and Moore references.

It is further noted that the references disclose disrupting many different types of biological materials. However, Zlobinsky discloses that various biological materials can be lysed using the claim-designated oscillating energy, including bacteria, plant tissue, animal tissue, muscle, leaves and skin, and that varying bead compositions including glass and zirconium silica oxide ceramic can be used. See col. 5, lines 27-36. It is also further noted that Cole-Parmer discloses, on page 539, both teflon and ground glass pestles. Moreover, Murphy et al disclose that a great variety of materials may be used to disrupt cells so that the DNA therein may be obtained. Thus, applicant's selection of specific materials for the claimed particles would have been considered obvious by the artisan of ordinary skill, the selection of a particular material being a matter of judicious choice on the part of the artisan of ordinary skill selecting from among a group of disclosed equivalents. Similarly, the selection of specific bead volumes, specific detergent amounts, etc., would have been considered by the artisan of ordinary skill to have been a matter of routine optimization, these parameters being routinely optimized in the art to effect a desired result.

Lastly, it is again noted that none of the references disclose the specific clearance between the side of the

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container and the spherical beads contained within. However, as the claims currently read the particles "comprise" one bead. This open language encompasses a process using many particles. Given the fact that the artisan of ordinary skill the time of applicant's invention would expect at least some of the particles to be, at some time, within the claimed distance of the interior wall of the container, this limitation is properly deemed to be met by any of the references. A holding of obviousness is clearly required.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 1-37 of U.S. Patent No. 6,235,501.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite processes comprising the same basic series of steps using the same starting materials. Moreover, the claims under examination are encompassed by the patented claims to the extent that the presently claimed DNA target product is encompassed by the patented nucleic acid target product. Moreover, the claimed DNA is clearly encompassed by the high molecular weight nucleic acid recited in the patented claims. Thus, the artisan of ordinary skill at the time of applicant's invention clearly would have considered the instant claims obvious in view of the patented claims. A terminal disclaimer is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can

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be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP  
September 6, 2002